GOVERNMENT OF THE PEOPLE'S REPUBLIC OF BANGLADESH
MINISTRY OF HEALTH AND FAMILY WELFARE
DIRECTORATE GENERAL OF DRUG ADMINISTRATION
Mohakhali, Dhaka-1212
www.dgda.gov.bd

CERTIFICATE OF REGISTRATION

We hereby declare that **Nimenrix powder and solvent for solution for injection in pre-filled syringe,** manufactured by **GlaxoSmithKline Biologicals S.A., Parc De La Noire Epine, Rue Fleming 20, 1300 Wavre, Belgium (also responsible for quality control & primary packaging) for Pfizer Limited, Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom. Site responsible for batch release: Pfizer Manufacturing Belgium NV, Rijksweg 12, B-2870 Puurs, Belgium** represented by **Radiant Export Import Enterprise, Lubdhok, 4th Floor, 474 P, Road No.-3, Sector-12, Uttara, Dhaka-1230, Bangladesh** is registered with Directorate General of Drug Administration & Licensing Authority (Drugs) under Registration Number ....366-6324-018..... The drug as described below is allowed to be imported into Bangladesh under **The Drugs Acts 1940 (XXIII of 1940) & The Drugs (Control) Ordinance, 1982, and its Amendment Act 2006**, subject to the provision of import policy published by the Government from time to time.

Name of Product : **Nimenrix**
(Meningococcal group A, C, W-135 and Y conjugate vaccine)
Dosage Form : Powder and solvent for solution for injection in pre-filled
Pack size : 1 vial (0.5ml) with Lyophilised Vaccine + 1 prefilled syringe with solvent

Composition:

Active Ingredients	**Specification**	**Quantities/units**
Neisseria meningitidis group A polysaccharide[1]	P.Eur.	5 micrograms
Neisseria meningitidis group C polysaccharide[1]	P.Eur.	5 micrograms
Neisseria meningitidis group W-135 polysaccharide[1]	P.Eur.	5 micrograms
Neisseria meningitidis group Y polysaccharide[1]	P.Eur.	5 micrograms
[1]Conjugated to tetanus toxoid carrier protein	P.Eur.	44 micrograms
Other ingredient(s)		
Powder:		
Trometamol	P.Eur.	97 micrograms
Sucrose	P.Eur.	28 milligrams
Solvent:		
Sodium Chloride	P.Eur.	4.5 milligrams
Water for injections	P.Eur.	q.s. ad 0.5 ml

Major General Md Mustafizur Rahman
Director General
Directorate General of Drug Administration
&
Licensing Authority (Drugs)
Government of the People's Republic of Bangladesh
Ph. 880-2-9880803, email: dgda.gov@gmail.com

06 NOV 2018

Instructions
To be dispensed only by or on the prescription of a registered physician.

Conditions:

1. Labelling should contain name and address of the Manufacturer, Batch number, Manufacturing date, Expiry date, M.R.P. (Maximum Retail Price), DAR No. (Drugs Administration Registration Number), (where applicable) etc. should be displayed on the label or container and also on the outer cover containing the container.
2. The registration will be valid for 5 (five) years from the date of issue unless it is revoked, suspended or cancelled earlier.
3. The certificate will be treated as cancelled in any viol ation of the conditions and the name or the formula of this product changed or modified qualitatively or quantitatively without due approval of the Licensing Authority.

Memo No. DA/15-5/13/366/ 24243 Dated 08/11/2018

07.11.18

For Director General
Directorate General of Drug Administration

c.c.to: M/s. **Radiant Export Import Enterprise**
Lubdhok, 4th Floor, 474 P, Road No.-3,
Sector-12, Uttara, Dhaka-1230